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10/089,696	07/24/2002	Yukoh Hiei	0760-0303 P	5503

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EXAMINER

HWU, JUNE

ART UNIT PAPER NUMBER

1661

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/089,696

Applicant(s)

HIEI ET AL.

Examiner

June Hwu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11, 13, 14, 16, 17, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12, 15, 18 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 13, 14, 16, 17, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 8, 11, 14, 17 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/24/02 &amp; 8/12/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The declaration and preliminary amendment filed July 24, 2002 are acknowledged and entered.
2. Applicants' election without traverse of Group I, claims 1-8, 10-11, 13-14, 16-17, 19 and 20 in the reply filed on March 8, 2006 is acknowledged.

### **Foreign Priority**

3. Acknowledgment is made of applicant's claim for foreign priority based on a PCT International Application No. PCT/JP00/05213 filed in Japan on August 3, 2000. It is noted, however, that applicants have not filed a certified copy of the priority documents from the International Bureau (PCT Rule 17.2(a)).

### ***Status of the Claims***

4. Claims 1-8, 10-11, 13-14, 16-17, 19 and 20 will be examined on the merits.

### ***Drawings***

5. The drawings are approved.

### ***Claim Objections***

6. Claims 8, 11, 14, 17 and 20 are objected to because of the following informalities: The claims start with an improper article. Appropriate correction is required.
7. Claims 8, 11, 14, 17 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

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required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically:

Claim 1 or 2 is drawn to a method of gene introduction into plant cells by *Agrobacterium* comprising centrifuging the plant cells or method of gene introduction of plant cells after centrifugation. Claim 8 is drawn to the method of preparing a plant. However, no limitations were recited in the claim. Thus, claim 8 fails to further limit claim 1 or 2.

Claim 13 is drawn to a method of gene introduction by centrifuging monocotyledon plant cells or plant tissues. Claim 17 is drawn to a method of preparing the family Gramineae. However, no limitations were placed on any method steps. Thus, claim 13 fails to further limit claim 13.

Claim 19 is drawn to a method of gene introduction by centrifuging rice or maize plant cells or plant tissue. Claim 20 is drawn to a method of preparing rice or maize. However, no limitation was placed on the method steps. Thus claim 20 fails to further limit claim 19.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-5, 8, 10, 11, 13, 14, 16, 17, 19 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-12, 14, 15, 17, 18, 20, 21, 23 and 24 of copending Application No. 10/089695. Methods comprising centrifuging plant cells or plant tissue originating from angiosperm and monocots, as claimed in the instant application are obvious over the methods of centrifuging plant cells or plant tissue originating from angiosperm and monocots, as claimed in the co-pending application.

This is a provisional obviousness-type double patenting rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-8, 10-11, 13-14, 16-17, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The method steps of centrifuging plant cells or plant tissue prior to the introduction of *Agrobacterium* are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The instant claims are broadly drawn to a method of promoting gene introduction comprising centrifuging plant cells and plant tissues. The instant claims only describe the method of gene introduction by centrifugation the plant cells or plant tissue before gene introduction but does not disclose the process of plant cells or plant tissue preparation and gene introduction.

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The instant specification provides detailed steps as to the types and size of the starting material (page 12, last paragraph continuing to page 13), centrifugation treatment such as speed of the centrifuge (page 13, 1<sup>st</sup> full paragraph), infection of the immature embryos with *Agrobacterium* (page 13, 2<sup>nd</sup> full paragraph), and co-culturing of the tissues (page 14, lines 1-9), selection of the transformed cells (page 14, 1<sup>st</sup> full paragraph through page 15), and finally regeneration of the transformants (page 15, 1<sup>st</sup> full paragraph). Moreover, Dodds et al (Experiments in Plant Tissue Culture, 2<sup>nd</sup> ed. 1988, pp. 139-141) discloses procedures of purification of protoplast.

Thus the lack of method steps in gene transfer comprising such as types of starting material, centrifugation treatment, infection and co-culturing, selection of the transformed cells, and the regeneration of the transformed cells are essential to practice the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 11 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections.

Claim 11 lacks antecedent basis for its recitation of "the method according to claim 9".

Claim 14 lacks antecedent basis for its recitation of "the method according to claim 11," which is dependent on claim 9.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 3, 4, 6, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Forreiter et al (The Plant Cell, 1997, vol. 9, pp. 2171-2181).

Forreiter et al. discloses a method of gene transfer *Arabidopsis thaliana*, an Angiosperm, cells by *Agrobacterium* comprising centrifuging the cells for one minute at 600G (page 2178, 6th paragraph).

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-3, 6, 8, 10, 11, 13, 14, 16, 17, 19 and 20 are rejected under under 35 U.S.C. 102(e) as being anticipated by Konzak et al (U.S. Patent 6,362,393).

Konzak et al disclose a method of centrifuging plant tissues (col. 4, lines 6-9) of rice or corn (col. 6, lines 29-32) at the acceleration of 100G for 3 minutes (col. 16, line 1) prior to gene introduction. Moreover, Konzak et al teach that gene transformation could occur at any time of the procedure (col. 4, lines 30-36) by using *Agrobacterium tumifaciens* (col. 12, lines 53-56).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. Claims 1-8, 10-11, 13-14, 16-17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Konzak et al in view of Forreiter et al.

The claims are drawn to a method of gene introduction comprising centrifuging at an acceleration of 100G to 250,00G, wherein the centrifugation occurs for 1 second to 4 hours, to plant cells or plant tissue of rice or maize (plants from family Gramineae, a monocot and an angiosperm), before gene transfer utilizing *Agrobacterium*.

The teachings of Konzak et al are discussed above.

Konzak et al do not teach the centrifugation speed of 500G to 200,000G.

The teachings of Forreiter et al. are discussed above.

It would have been obvious to one of ordinary skill in the art to use the method of promoting gene introduction into plant cells by centrifuging the plant cells or plant tissues before gene introduction by applying *Agrobacterium* as taught by Konzak et al, and to modify that method by adjusting the centrifugal acceleration as taught by Forreiter et al given the advantage of separating the tissues at higher speed. One would have been motivated to do so, given the effectiveness of separating plant tissue cells by centrifugation. The rate and time of the centrifugation is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for a skilled artisan to determine the optimal rate and time in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of rate and time of centrifugation would have been obvious at the time of Applicants' invention.



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Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### **Conclusion**

14. No claims are allowed.

### **Correspondence**

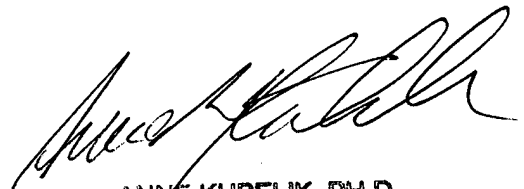
Any inquiry concerning this communication or earlier communications from the examiner should be directed to June Hwu whose telephone number is (571) 272-0977. The Examiner can normally be reached Monday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June Hwu

April 27, 2006



ANNE KUBELIK, PH.D.  
PRIMARY EXAMINER